Appendix C

Performance Tests for Dental Units
Intraoral and Panoramic

A. Requirements For Dental Intraoral Units

1. ***Exposure and Timer Reproducibility***

a. Purpose: To ensure that exposure received for the same mA, time, and kVp is the same from exposure to exposure.

b. Regulations: Determination of reproducibility is based on five consecutive measurements within a time period of thirty minutes, using the same technique factors. The exposures must have a coefficient of variation (CV) less than 5%. Reference: 21 CFR 1020.31(b)(1).

c. Equipment: Ion chamber.

d. Procedure:

(1) Place the probe 10 inches from the focal spot as marked on the tube head.

(2) Visually center the probe in the beam, checking from the front and the sides to ensure that the beam will strike the probe. Once established, this set up should not be varied during this test.

(3) Select the most commonly used patient technique and make five exposures, rotating all dial settings between exposures. Always wait at least 30 seconds between exposures so as not to overheat the tube.

(4) Record the pulse exposure in mR (milliRoentgen) and the pulse duration in msec (milliseconds).

e. Interpretation of results: The exposures must have a coefficient of variation (CV) less than 5%. See section 1 of Appendix B for calculation of CV. If all values are within a few mR of each other, this calculation is not necessary.

2. ***Timer Accuracy***

a. Purpose: To ensure that the x-ray generator is producing the exposure time as set on the control panel.

b. Regulations: The accuracy of the timer should be within 10% of the selected setting.

c. Equipment: Same as above.

d. Procedure: Keep the same set-up as for reproducibility, holding kVp and mA constant. Select three commonly used patient timer settings by consulting either the technician or the technique chart. Make an exposure at each setting, recording mR and msec.

e. Interpretation of results: Pulse duration measured should be within 10% of the nominal setting or as specified by the manufacturer. Also, pulse exposure should increase linearly with time, i.e., exposure should increase by approximately the same percentage as the time is increased.

3. ***Linearity of mR/mAs***

(Please note that this test cannot be done on fixed kVp or mA units.)

a. Purpose: To ensure that similar exposures are obtained for the mAs and kVp regardless of the exposure time and mA.

b. Regulations: The average ratios of exposure to indicated mAs (mR/mAs) obtained at two tube current settings should not differ by more than 0.10 times their sum.

c. Equipment: Same as above.

d. Procedure:

(1) With the equipment in the same set-up as above, record one of the reproducibility results as the first reading.

(2) Switch to another mA station if one exists while holding kVp and timer settings constant.

(3) Make an exposure and record pulse exposure, then divide mR output by mAs setting.

(4) Record this mR/mAs as calculated.

e. Interpretation of results: These two mR/mAs results should be similar, specifically the difference between the two divided by sum of the two should not exceed 10%. Repeat this test at several kVp settings.

4. ***kVp Accuracy and Precision***

a. Purpose: To ensure that the x-ray generator is producing the kVp as indicated on the control panel.

b. Regulations: The accuracy must be within 5 kVp of the control panel setting (Some units have fixed kVp and must be within 5 kVp of that value).

c. Equipment: kVp meter.

d. Procedure:

(1) Select the proper phase switch on the kVp meter (most dental units are single phase).

(2) Center the end of the cone on the kVp meter so that the x-ray field will cover the required area of the kVp meter.

(3) Check 90 kVp at one-half second, 80 kVp at one second and 70 kVp at two seconds. Four measurements should be obtained at the most clinically used setting.

(4) For fixed kVp units, determine the actual kVp.

(5) Allow for tube cooling between longer shots, e.g., one minute for one second, two minutes for two seconds, etc.

e. Interpretation of results: The meter reading should be within five kVp of each setting. The coefficient of variation should be less than 0.02.

5. ***Beam Quality (Half-Value Layer (HVL) Determination)***

a. Purpose: To assure that the permanently installed filtration at the x-ray tube is maintained at an appropriate level to help minimize patient exposure.

b. Regulations: The minimum value of the HVL shall be as stated in Table B-1 for the actual kVp determined above.

c. Equipment: Electrometer with small ion chamber, sheets of type 1100 alloy aluminum

d. Procedure:

(1) Set the control console for 80 kVp, if the unit does not have fixed kVp.

(2) Take an exposure using the set-up for the reproducibility test.

(3) Measure the radiation and record the value as the exposure with zero mm Al added.

(4) Next, tape one mm Al (use tape which does not leave marks, such as paper surgical tape, or whatever is conveniently available) on the end of the cone and take a reading at the same settings, recording this for one mm Al added.

(5) Repeat for two, three and four mm of Al.

(6) Finally, remove all Al and take one last reading with zero mm Al. As a rule of thumb, the four mm trial is not needed if three mm cuts the initial reading in half. If the final exposure is not wilthin 2% of the initial exposure made with 0 mm of Al, repeat the measurement series ensuring that the technique and geometry selected remain the same throughout the procedure.

e. Interpretation of results:

(1) Use the average of the two zero readings as the unattenuated value.

(2) The HVL may be determined mathematically using logarithmic interpolation or graphically using semi-log paper. Refer to the general radiographic beam quality section for a description.

(3) The HVL must meet FDA standards for the actual kVp used which was determined above. FDA standards for half-value layers, for dental units, are included in Table B.1.

6. ***Source To Skin Distance And X-Ray Field Size/Cone Alignment***

a. Purpose: To determine the minimum source to patient distance and field size.

b. Regulation: The source to skin distance and field size shall be as stated in 21 CFR 1020.31(f)&(h).

c. Equipment: Measuring tape and fluorescent screen.

c. Procedure:

(1) Measure and record the length of the removable cone, the distance between the focal spot and end of the cone and the inner diameter of the cone.

(2) Use the fluorescent screen to ensure the x-ray beam at the end of the cone is the same size as the cone.

7. ***Entrance Skin Exposure (ESE)***

See chapter 15 and Appendix I.

B. Requirements For Dental Panoramic Units

1. ***Exposure Reproducibility***

a. Procedure: (Same as for the dental intraoral unit) The ion chamber must be secured to the chin rest with adhesive tape for measurement to be taken.

2. ***Duration of Exposure Cycle***

a. Purpose: To ensure that the x-ray generator is producing the exposure time set by the manufacturer.

b. Regulations: The accuracy of the timer should be as stated by the manufacturer.

c. Equipment: Stopwatch or electrometer with small ion chamber. Comment: The MDH model 1515 cannot be used for this test, as it will overrange.

d. Procedure:

(1) Select the most commonly used clinical technique. Make one exposure at this setting.

(2) Start and stop the stopwatch based on the tone which indicates radiation production.

(3) Record the exposure duration from the stopwatch in seconds.

(4) If the electrometer is used, secure the small ion chamber to the patient chin rest, using strong adhesive tape with the probe pointing up. (Since the machine will be moving during the exposure, the ion chamber and converter box must be secure. Dropping the ion chamber can cause extensive damage).

(5) Select the most commonly used clinical technique. Make an exposure at this setting. Record the exposure duration, using the pulse mode of the MDH.

3. ***Linearity of mR/mAs (Same as for dental intraoral unit)***

4. ***Beam Quality- Half Value Layer (HVL) Determination***

a. Purpose: To ensure that the permanently installed filtration at the x-ray tube is maintained at an appropriate level to help minimize patient exposure.

b. Regulations: The minimum value of the HVL shall be as stated in Table B-1, for the operating kVp of the unit.

c. Equipment: Electrometer with small ion chamber and sheets of varying thicknesses of type 1100 alloy aluminum.

d. Procedure:

(1) Secure ionization chamber to the patient chin rest securely, e.g., using strong adhesive tape with the probe pointing up. *[Since the machine will be moving during the exposure, the ion chamber and converter box must be secure]*

(2) Take a reading with the ionization meter in the exposure rate (mR/hr) mode. Record this as the exposure for zero mm of added aluminum.

(3) Tape one mm of Al to the face of the cone, take a second reading and record these results for one mm Al added. Repeat for two, three and four mm of Al. (the four mm test does not need to be done, if three mm cuts the original exposure rate in half).

(4) Remove all Al and take another reading. If the final exposure is not within 2% of the initial reading made with 0 mm Al, repeat the measurement series ensuring that the technique and geometry remain the same throughout the procedure.

(5) Comment: There are procedures to keep the unit from rotating during exposure. However, these are usually invasive, and require the assistance of a dental repair technician. They are not recommended for radiation safety surveys of dental panoramic units.

e. Interpretation of results:

(1) Use the average of the two readings using zero mm Al as the unattenuated value. The HVL may be determined mathematically using logarithmic interpolation or graphically using semi-log paper. Refer to the general radiographic beam quality section for a complete description. Interpolate to find the thickness of Al which reduces the mR output to half of the unattenuated reading. This approximates the HVL of the beam (See Figure B-1).

(2) The HVL must meet FDA standards (Table B-1) for the kVp indicated on the unit.

5. ***X-Ray Beam/Film Slit Alignment***

a. Purpose: To ensure that the x-ray beam and film slit are in alignment.

b. Regulations: The beam dimensions shall not exceed the film slit opening.

c. Equipment: Fluorescent screen or intraoral film and tape.

d. Procedure:

(1) This may be done in real time by using a piece of the fluorescent screen which should be taped to the film holder covering the film slit. Mark the outline of the film slit on the screen. Dim the room lighting and position yourself so that the screen can be seen. Make an exposure and watch for the entire film slit area to glow green.

(2) The film slit alignment may also be recorded on film for documentation as follows:

(a) Tape two pieces of intraoral film across the film slit diagonally, one at the top and one at the bottom of the slit, or a piece of ready pack film across the film holder.

(b) Mark them using a pin to prick the film at the edge of the slit opening and make an exposure only a few seconds in duration.

(c) Develop the film.

e. Interpretation of results:

(1) Fluorescent screen: Entire film slit should be seen.

(2) For film, a diagonal line should be seen across each film from corner to corner or between pin marks.

(3) Record whether satisfactory, or unsatisfactory.

6. ***Entrance Skin Exposure***
(see chapter 15 and Appendix I)